EXHIBIT I

In the Matter Of:

NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION

VIDEOTAPED DEPOSITION OF DEBRA SCHAMBERG, R.N.

February 04, 2015

DISCOVERY
LITIGATION SERVICES
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100 Mayfair Royal
181 Fourteenth Street
Atlanta, GA 30309
404.847.0999

Q. Well, let me -- let me hand you a document that we'll make Exhibit No. 27, and this is STOPNC_889 and the subsequent pages. I'll hand that to you.

(Exhibit 27 was marked for identification.)

THE WITNESS: Okay.

Q. (By Mr. Nolan) Can you tell us what that is.

A. This is an e-mail that I exchanged with Bruce Stock of Henry Schein.

Q. Okay. And what is Henry Schein?

A. It's a supplier of medical supplies.

Q. Okay. And this is an e-mail dated in July 2011; is that correct?

A. Correct.

Q. And at that time, you tell Mr. Stock that "We average 450 to 500 procedures a month." Do you see that?

A. Yes.

Q. And are those procedures epidural steroid injections?

A. Yes.

Q. And then you give him a list of medications about which you are apparently making pricing inquiries; is that right?

A. That is correct.

Q. And is inquiring about price one of the ways that you would help Howell Allen Clinic control the costs at St. Thomas Neurosurgical?

A. Well, yes.

Q. Okay. And so -- and you indicate that you-all used 500 to 700 vials of either Depo-Medrol or methylprednisolone, 80 milligrams a month; is that correct?

A. That is correct.

Q. So does that refresh your memory about generally how many procedures that you were doing at that period of time?

A. Yes, that seems correct.

Q. What -- would I be correct in understanding that epidural steroid injections comprises the overwhelming majority of revenues generated at St. Thomas Neurosurgical?

A. Yes, I believe it does.

Q. And what percentage of revenues would you estimate are attributable to epidural steroid injections as opposed to some other procedure?

A. Now, I don't -- I don't have the percentages. To what other procedures are we...

Q. Well, you mentioned the stem trials and the

denervations.

A. Okay.

Q. And I understand -- I'm not asking you for an exact number.

A. Okay.

Q. And if you don't know, just say that. But my question is what's your estimate of the percentage of revenues that are attributable to epidural steroid injections?

A. I probably -- I can't answer that for sure.

Q. And St. Thomas Neurosurgical provides epidural steroids to patients in exchange for money; correct?

A. That is correct.

Q. And it's a for-profit entity, St. Thomas Neurosurgical; is that correct?

A. That is correct.

Q. Now, you understand that a steroid, which is at issue in this litigation is known as -- I might mispronounce it and if I do, I apologize. But I say methylprednisolone acetate. Have I said it correctly?

A. Yes.

Q. And it's abbreviated MPA; is that correct?

A. That is correct.

Q. Who is it that decided that St. Thomas

Neurosurgical would purchase MPA from New England Compounding Center, what we call NECC?

A. That was -- after conferring with Dr. Culclasure, it was his decision and my decision.

Q. So other than you and Dr. Culclasure, were there any other persons employed by Howell Allen Clinic or St. Thomas Neurosurgical or any of the other -- well, any other persons other than you and Dr. Culclasure who made that decision?

A. No.

Q. Why did you and Dr. Culclasure decide that St. Thomas Neurosurgical would buy MPA from NECC?

A. There was a shortage of MPA. MPA also from NECC offered a true preservative-free in their steroid.

Q. All right. Any other reasons?

A. Those are the main reasons.

Q. Price was not a primary factor; is that true?

A. That's true.

Q. Tell us about the shortage.

A. We had ordered from our other vendor and were unable to get the quantity that we needed.

Q. Okay. Who was your other vendor?

A. We were using Clint.

procedures as to what to do in the event of a medication shortage?
A. Yes, we do.
Q. And tell us -- tell us what you're supposed to do when confronted with a medication's shortage.
A. Not without reading.
Q. So as we sit here today, am I correct that you do not have an independent memory as to what is required from a policy standpoint if you're confronted with a medication shortage?
A. I'm going to consult with my medical director and we'd go from there.
Q. All right. Let me hand you a document we're going to make Exhibit No. 42. It's STOPNC_308. And ask you if this is, in fact, a copy of the policy that you mentioned.
(Exhibit 42 was marked for identification.)
THE WITNESS: Yes, it is.
Q. (By Mr. Nolan) You see where the policy requires that you communicate the shortage and practice changes to all personnel?
A. Yes.
Q. Okay. And was that done as far as this shortage that motivated you to start buying from NECC?

A. The staff knew that there was a shortage, yes.
Q. All right. And how was it communicated to the staff?
A. Verbally.
Q. Is there anything in writing that shows that a shortage was communicated to the staff?
A. I -- not that I -- I don't know. I don't remember.
Q. Is there anything in writing indicating that the shortage was communicated to the board or the medical executive committee?
A. Not that I recall.
Q. Did -- did the clinic have any procedure for making changes on the formulary, adding a drug to the formulary, for example?
A. If a drug needed to be added to the formulary, we would submit a -- the medical director would sign off on a -- for the request and it would be submitted to the board.
Q. Okay. Submitted to the board?
A. Well, the MEC and I guess the board, both.
Q. And so was it your understanding that both the medical executive committee and the board had to approve any changes to the formulary?

A. If we were adding or deleting medication to the formulary, it went to the --
Q. All right. And so is that level of review by those two different committees also a matter of patient safety?
A. I would assume so.
Q. Let me hand you a document we'll make Exhibit No. 43, which is STOPNC_307 and I'm going to ask you to tell us what this is.
(Exhibit 43 was marked for identification.)
THE WITNESS: It's the -- or formulary drug evaluation request.
Q. (By Mr. Nolan) So is this a form that would be completed if someone wanted to add a drug to the formulary?
A. Yes.
Q. Okay. And so this -- this form would be filled out and then it would be approved by the medical director, the medical executive committee, as well as the board of St. Thomas Neurosurgical; is that correct?
A. That is correct.
Q. All right. That process was never undertaken with respect to your decision and

Dr. Culclasure's decision to begin purchasing from NECC; is that true?
A. We did not use this for NECC.
Q. Do you know why changes to the formulary require, I guess, three levels of review, the medical director, the medical executive committee and ultimately the board?
A. It just goes through the chain of command to make sure everyone knows.
Q. And would you agree that adding drugs for use in the clinic without appropriately amending the formulary and going through that review could be dangerous for patients?
MR. GIDEON: Objection to the form.
THE WITNESS: Not necessarily, I don't.
Q. (By Mr. Nolan) Did you ever talk with a pharmacist named Martin Kelvas at St. Thomas Hospital?
A. Not that I recall.
Q. What about Carmen Leffler?
A. Not that I recall.
Q. How did you first learn that there was a problem in September -- I think you said on September the 18th, 2012? How did you first become aware that there was a problem with a potential meningitis issue?

A. I received a call from Candace Smith, who is the infection prevention nurse at St. Thomas Hospital.
Q. All right. And now that you bring up Ms. Smith, you knew Ms. Smith before she called you that day; is that correct?
A. That is correct.
Q. In fact, she would actually help St. Thomas Neurosurgical with some of its infection control measures; is that true?
A. That is correct.
Q. Okay. And she is an employee of whom?
A. St. Thomas Hospital.
Q. Okay. And so why is it that a St. Thomas Hospital employee would help St. Thomas Neurosurgical with its infection control procedures?
A. That's not uncommon. I could talk to someone at Baptist or Skyline, anywhere.
Q. All right. But did anyone other than Ms. Smith from St. Thomas Hospital come in and assist St. Thomas Neurosurgical with infection control issues before the outbreak?
A. Just there may have been somebody in her department, but, no, I -- there was no need for it.
Q. Okay. What sort of infection control

measures were used at St. Thomas Neurosurgical?
A. Rephrase that. What are you --
Q. Tell us what types of infection control measures were used at St. Thomas Neurosurgical.
A. I mean, you -- you're always monitoring your infection control on a day-to-day procedural basis.
Q. And explain those procedures to us.
A. You make sure sterile technique is used, that rooms are being cleaned and that protocol is being followed as best could -- that it can be.
Q. And what sterile techniques are you referring to?
A. For the procedures. When the physician is doing the procedure.
Q. So does the physician wear sterile masks?
A. Not sterile masks.
Q. Do they wear gloves?
A. They wear sterile gloves.
Q. And a gown?
A. Not for an epidural, a gown is not needed.
Q. All right. So what sterile materials are used for an epidural steroid injection?
A. An epidural tray, the needles, supplies in the tray, sterile gloves, you're cleaning the patient.

You cannot sterilize the skin, but you can cleanse the skin.
Q. And so all of those essential procedures were set out in writing, I assume; is that correct?
A. The guideline, they have a guideline to...
Q. And Ms. Smith, would she come over and periodically inspect your procedures and sterility protocols and help you --
A. No.
Q. All right. Well, what exactly was her role as far as infection prevention at St. Thomas Neurosurgical?
A. She had no role. She -- if I had a question, I could call her and ask her.
Q. But did she ever get paid to come over and help you-all with infection control?
A. No.
Q. That never happened?
A. Not that I'm aware of.
Q. All right. So we took a sidetrack. You indicated that you first received a call from Ms. Smith on September 18th. Tell us the story. What happened next?
A. Ms. Smith called, told me that there was a patient that had been -- she had been notified that

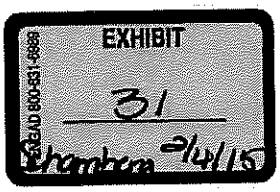
the patient had Aspergillus fungal infection and that she was checking to see if that patient was treated -- had an epidural at St. Thomas Outpatient Neurosurgical Center.
Q. And what happened next?
A. I was on vacation so I notified -- sent an e-mail to Dr. Culclasure to please check the following day to see if that is a patient of ours, if he was a patient of ours.
Q. Did he do that?
A. Yes, he did.
Q. And what happened next?
A. He responded to me that he had -- that, yes, this gentleman was a patient of ours, but he had -- in reading his record, his office record note, that he had -- this patient had been seen in the ER at St. Thomas Hospital to rule out Rocky Mountain spotted fever.
Q. All right. And what happened next?
A. That was on Wednesday. On -- there again, I'm on vacation. I'm going by what I was told. But on Thursday, they were informed that two more patients had become ill. So we voluntarily stopped procedures until we could figure out what's going on.
Q. All right. And so was that September 20th?

From:	Jason Salvucci <jsalvucci@medicalsalesmgmt.com>
Sent:	Monday, September 27, 2010 9:39 AM
To:	Debra Schamberg
Subject:	quote
Attachments:	new quote form; NECC FLYER - Methylprednisolone Preserved and Preservative-Free.pdf; NECC FLYER - Preservative-Free Hyaluronidase.pdf; NECC FLYER - Triamcinolone Preservative Free.pdf; NECC FLYER - Celestone Soluspan - Preserved or Preservative Free.pdf; NECC FLYER - Innovations in Pain Management - Preservative Free.pdf; NECC FLYER - Crash Cart Medications.pdf; NECC SOP - General Overview of Policies & Procedures for Compounding Sterile Products.pdf; NECC FLYER - Radiopaque Dye Repackaging.pdf; NECC FLYER - Radiopaque Dye Repackaging.pdf; NECC FLYER - Radiopaque Dye Repackaging.pdf

Debra

It was nice to meet you in Franklin at the show, Hopefully you aren't too busy today. Thanks for stopping our booth. Here is some information that was in our folder. The first one is the quote and the others are some general information for you, If you have any questions please let me know.

Thanks



Jay Salvucci
Account Manager
NECC (New England Compounding Center)
508-656-2610 (direct)
774-292-1281 (cell)
jsalvucci@medicalsalesmgmt.com
www.neccrx.com
www.ameridose.com

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Fax: 888.820.0583 or 508.820.1616
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To: Debra

Howell/Allen
Phone: 615-341-3433
Fax: 615-341-3427
Email-dschanberg@howellallen.com

From: Jay Salvucci
Phone: 800-994-6322, Ext. 610
Direct: 508-656-2610
Fax: 888-820-0583

Subject: Pricing

Date: 09/27/2010

Dear Debra

Thank you for your interest in NECC. Per your request, please find below the pricing information we discussed.

Medication	Strength	Size	Quantity	Exp. Date	Storage	Pricing
Omnipaque	180	5ml	500+	180 days	Room Temp	$14.00

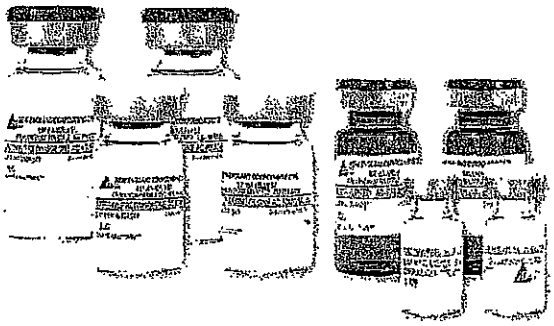
180 days beyond use date from date of compounding. Quotation is good for 30 days.

If you have any questions, please call me directly at the number listed above.

Jay Salvucci
Account Manager
NECC (New England Compounding Center)
508-656-2610 (direct)
774-292-1281 (cell)
jsalvucci@medicalsalesmgmt.com
www.neccrx.com

Methylprednisolone Acetate

- **Available Preserved or Preservative-Free in 40mg/mL & 80mg/mL**
- **Preserved** is Available in 5mL & 10mL Vials
- **Preservative-Free** is Available in 1mL, 2mL & 5mL Vials
- Beyond Use Date: 6 Months
- Storage: Room Temperature



All CSP Formulations are:

- USP 797 Compliant
- Compounded for your patients by pharmacists extensively trained in aseptic compounding
- Prepared in a Class 10 Microenvironment (barrier isolator)
- Comprised of USP quality ingredients

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NECC's Preservative-Free Hyaluronidase is:

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- Cold Shipped

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- Medications are prepared in a Class 10 Microenvironment (barrier isolator)
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- Storage: Room Temperature

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NECC Provides a Compounded Formulation of Betamethasone Repository

- **Available Preserved or Preservative-Free**
- 3mg Betamethasone Acetate with 3mg Betamethasone Sodium Phosphate per mL
- **Preserved** is Provided in a 5mL or 10mL Vial
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for prescribers needing…….	*we compound preservative-free*
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Celestone Soluspan®	Betamethasone acetate 3 mg/ml betamethasone.Na phosphate 3 mg/ml
Celestone Phosphate®	Betamethasone phosphate
Depomedrol®	Methylprednisolone acetate
Kenalog®	Triamcinolone acetonide

If you need any medication that is discontinued, backordered or not manufactured in the strength or form required, please call us.

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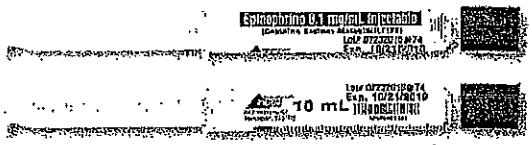
Crash Cart Medications

NECC Provides the Following Medications for Crash Carts:

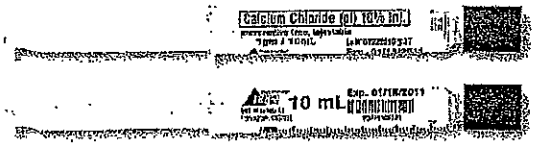
Epinephrine

- Available in 0.1mg/mL
- Provided in a 10mL Luer-Lock Syringe with a Tamper Evident Cap
- Beyond Use Date: 90 Days
- Storage: Room Temperature



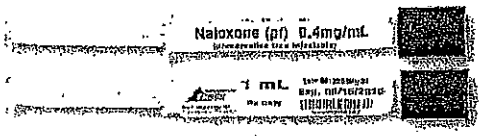
Calcium Chloride

- Available in 100mg/mL (10%)
- Provided in a 10mL Luer-Lock Syringe with a Tamper Evident Cap
- Beyond Use Date: 180 Days
- Storage: Room Temperature



Naloxone

- Available in 0.4mg/mL
- Provided in a 3mL Luer-Lock Syringe with a Tamper Evident Cap
- Beyond Use Date: 180 Days
- Storage: Room Temperature



NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers. NECC is USP Chapter 797 compliant. Pharmacists formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility.

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General Overview of Policies & Procedures for Compounding Sterile Products

NECC operates in accordance with the following general guidelines when compounding sterile products:

A. Facility/Equipment

a. Class 10 Microenvironments (barrier isolator).
b. Certified by Massachusetts Board of Pharmacy as a pharmacy with a central venous admixture service (CIVAS) in accordance with Board regulations, 247 CMR 6.01 (6) (c).

B. Monitoring & Maintenance

Class 10 Microenvironments validated every 6 months by an independent vendor.

C. Personnel

a. All sterile compounding is performed by properly trained and validated registered pharmacists.
b. Pharmacy personnel are trained/validated by an outside agency, Professional Compounding Centers of America (PCCA).
c. Personnel are validated on a quarterly basis.

D. Quality Assurance/Quality Control

a. USP Chemicals are obtained only from FDA registered facilities.
b. Formulations are sterilized by either filtration through a 0.22 micron filter or by autoclaving.
c. Samples from final product batch lots are sent to an independent FDA registered analytical lab for sterility, endotoxin (pyrogenicity) and potency testing.
d. Tested medication is quarantined and dispensed only after the sample has tested negative for endotoxin and microbial contamination.
e. The Quality Assurance Team (QAT), made up of employees from all departments within NECC, meets regularly to review all quality related items.

f. NECC maintains strict environmental testing protocols. Results of these tests are reported at all QAT meetings.
g. All sterile compounding actions are performed in compliance with NECC's Standard Operating Procedures (SOPs). These SOPs have been "mapped" against USP 797 "Pharmaceutical Compounding – sterile preparations" to ensure that all USP 797 requirements are observed.

E. Use-by Dating

Each vial is labeled with a use-by date appropriate to the formulation obtained from:

- Current literature
- Independent stability assay

F. Packaging

a. Compounded preparations are packaged in containers meeting USP standards.
b. Container used depends on the physical and chemical properties of the compounded preparation.

G. Dispensing

Product is dispensed by patient-specific prescription only. There must be a specific practitioner-patient-pharmacist relationship to dispense to an individual patient or facility.

H. Shipping

Medications are shipped overnight (usually via FedEx) in an appropriate container to ensure controlled temperatures and product integrity.

I. Licensing

NECC has undertaken a rigorous licensure process thus giving us the ability to legally dispense prescription medication in all 50 states.

UNIT-DOSE REPACKAGED RADIOPAQUE DYES

Aseptic Repackaging Service Provided by NECC

Repackaged Isovue™ or Omnipaque™ in a 5ml Sterile Vial

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From: John Notarianni [jnotarianni@medicalsalesmgmt.com]
Sent: Friday, March 25, 2011 9:05 AM
To: Debra Schamberg
Subject: NECC

Attachments: Celestone Soluspan - Preserved or Preservative Free.pdf; Triamcinolone Preservative Free.pdf; NECC Overview.pdf
Hello Debra

I would like to provide your facility with pricing on some of the medications you are currently using. Also if you are having any trouble getting Celestone we can supply you with Betamethasone Repository. Please give me the opportunity to create a cost savings for your facility, and provide you with an outlet for backordered drugs. I need five minutes of your time to identify the value NECC can bring to your facility. I have attached a couple of product flyers for your review. Please email or contact me via cell phone, at your convenience. I look forward to providing you with the best service I can.

Thank you and I hope you have a blessed day.

John L. Notarianni
Regional Sales Manager
Medical Sales Management
Representing: **NECC**
Cell Phone: (508)454-0779
Fax: (508) 820-9401
jnotarianni@medicalsalesmgmt.com
www.Neccrx.com

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- **Preserved** is Provided in a 5mL or 10mL Vial
- **Preservative-Free** is Provided in a 2mL and 5mL Vial
- Beyond Use Date: 6 Months
- Storage: Room Temperature

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STOPNC_0151

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NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers. NECC is USP Chapter 797 compliant. Pharmacists formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility.

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Company Overview

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NECC Allows you to Order Medication not Available from a Pharmaceutical Manufacturer Due to:

- Discontinuation of Commercial Medication
- Prolonged Back Order
- Product not available in Dosage Form, Strength or Content Needed for Patient

Why NECC?

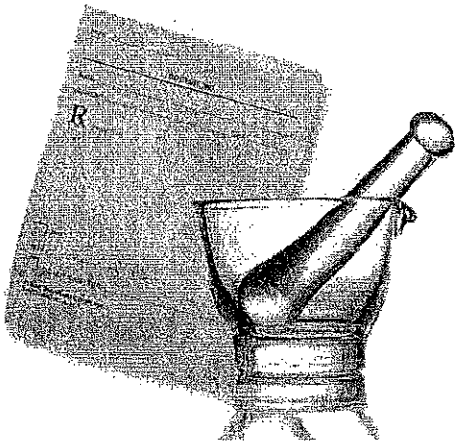
- Wide Range of Compounded Preparations
- Reliable Extended Beyond Use Dating
- Customization to meet your Patient's or Facility's needs
- Bar Coding
- Quarterly QA Reporting

Equipment and Facility

- State-of-the-Art Nationally Licensed Compounding Facility
- Class-1,000 (ISO-6) Cleanrooms
- Class-10 (ISO-4) Isolation Chambers / Glove Boxes

Personnel

- Highly Specialized and Extensively Trained Compounding Pharmacists and Certified Technicians
- Experienced Formulation Research and Development Team



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From: John Notarianni [jnotarianni@medicalsalesmgmt.com]
Sent: Wednesday, May 04, 2011 8:04 PM
To: Debra Schamberg
Subject: NECC

Attachments: Howell Allen ASC Nashville TN.docx
Hello Debra

It was a pleasure speaking with you today. Please review the pricing on the medications we spoke about. I look forward to our follow up and hope you will consider working with NECC to bring value to your facility.

Thank you

John L. Notarianni
Regional Sales Manager
Medical Sales Management
Representing: **NECC**
Cell Phone: (508)454-0779
Fax: (508) 820-9401
jnotarianni@medicalsalesmgmt.com
www.Neccrx.com

NECC - ***A vital resource for sterile and non-sterile compounding medications.***

John L. Notarianni
697 Waverly Street, Framingham, MA 01702
Tel: 508.454.0779
Fax: 508.820.1616
jnotarianni@medicalsalesmgmt.com
www.neccrx.com

To:	Howell/Allen ASC 4230 Harding Road Suite 901 Nashville, TN 37205 Attn: Debra Schamburg	Telephone: Fax: Email:	615-341-3433 dschamberg@howellallen.com

From:	John L. Notarianni Regional Sales Manager Medical Sales Management Representing: NECC
Subject:	Necc
Date:	5-4-2011

Dear Debra

Thank you for your interest in NECC. Per your request, please find below the pricing information for the items we discussed.

Medication	Strength	Size	Quantity	Exp. Date	Storage	Pricing
Methylprednisolone (PF)	80mg/ml	1ml	500 per month	6months	Room Temp _X__ Refrigerated___ Frozen ___	$8.00ea
Methylprednisolone (PF)	80mg/ml	2ml	200 per month	6months	Room Temp _X__ Refrigerated___ Frozen -20 ___	$13.00ea
Omnipaque 300		5 ml	500 per month	6months	Room Temp _X__ Refrigerated___ Frozen -20 ___	$14.00ea
Omnipaque 300		3 ml	500 per month	6months	Room Temp _X__ Refrigerated___ Frozen -20 ___	$11.00ea

Beyond use date from date of compounding. Quotation is good for 30 days.

If you have any questions, please call me directly @ 508-454-0779.

Best Regards,

John L. Notarianni
Regional Sales Manager
Medical Sales Management
Representing: NECC
Cell Phone: (508) 454-0779
Fax: (508) 820-9401
jnotarianni@medicalsalesmgmt.com
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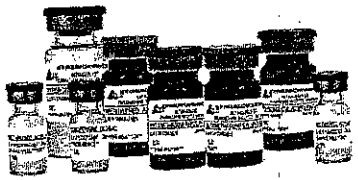
Surgery Centers

For Prescribers Needing:	We Compound Preservative-Free:
Wydase®	Hyaluronidase
Celestone Soluspan®	Betamethasone Acetate 3mg/mL Betamethasone.NA Phosphate 3mg/mL
Celestone Phosphate®	Betamethasone Phosphate
Depomedrol®	Methylprednisolone Acetate
Kenalog®	Triamcinolone Acetonide



All CSP Formulations are:

- USP 797 Compliant
- Compounded for your patients by pharmacists extensively trained in aseptic compounding
- Prepared in a Class 10 Microenvironment (barrier isolator)
- Comprised of USP quality ingredients

NECC (New England Compounding Center) is a compounding-only [illegible] providing the highest quality compounded medications

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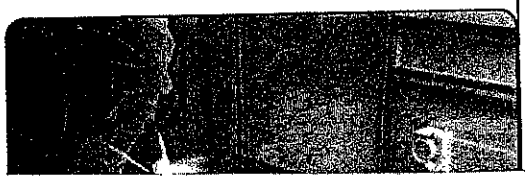
COMMITMENT TO QUALITY

All Formulations are:

- USP 797 Compliant
- Strictly Enforced Environmental Monitoring Program
- Comprehensive End-Product Testing Program

(Independent Analytical Laboratory Used for ALL End-Product Testing)

- Sterility Testing
- Endotoxin Testing
- Quantitative Testing
- Extended Stability Testing



Surgery Centers

For Prescribers Needing:	*We Compound Preservative-Free:*
Wydase®	**Hyaluronidase**
Celestone Soluspan®	**Betamethasone Acetate 3mg/mL** **Betamethasone.NA Phosphate 3mg/mL**
Celestone Phosphate®	**Betamethasone Phosphate**
Depomedrol®	**Methylprednisolone Acetate**
Kenalog®	**Triamcinolone Acetonide**

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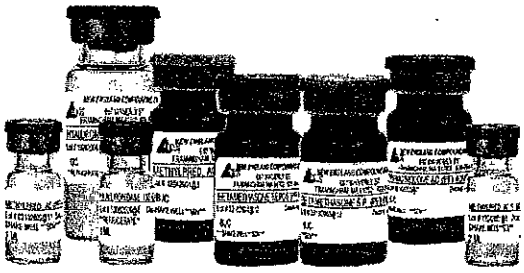

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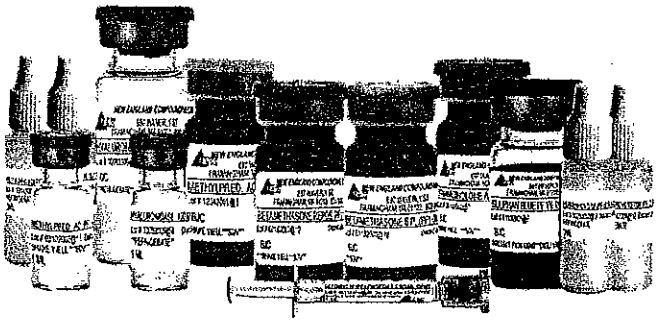

Surgery Center
CUSTOM MEDICATIONS

Steroids (Preservative-Free)	Methylprednisolone Acetate, Triamcinolone Acetonide, Betamethasone Repository, Betamethasone Sodium Phosphate "Particulate - Free", Dexamethasone Sodium Phosphate "Particulate - Free"
Neurolytic Agent	Phenol 6-10% / Glycerol (Inj)
Diagnostic Dye	Sulphan Blue 1% (PF)
Ophthalmic	Hyaluronidase (150u/mL), Mitomycin Topical
"Pre-Cataract" Dilation Drops (Preservative-Free)	(PE) Phenylephrine (T) Tropicamide (C) Cyclopentolate (K) Ketorolac #1) PE-T-C 2.5%-1%-1% #2) PE-T-C 10%-1%-1% #3) PE-T-C-K 2.5%-1%-1%-0.5% #4) PE-T-C-K 10%-1%-1%-0.5%
Anesthetic Solution	Topical ("Cocaine" 4%, 4mL)

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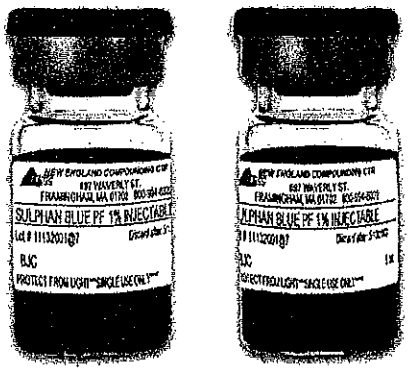
Sulphan Blue

- Injectable, Preservative-Free 1% Solution
- Provided in a 5mL, Single - Dose Vial
- Beyond Use Date: 180 Days
- Storage: Room Temperature



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Cocaine HCL 4% Topical Solution

*Sterile

- 4ml Volume
- Provided in a 5ml Amber Glass Vial with a Flip-Top Cap

All Formulations Are:

USP 797 / 795 Compliant

All formulations are compounded for your patients by pharmacists & technicians extensively trained in aseptic compounding

Medications are comprised of USP quality ingredients

Dedicated to Providing the Highest Quality Compounded Medications and Service to Patients and Prescribers

Please call today to discuss your patient's prescription needs

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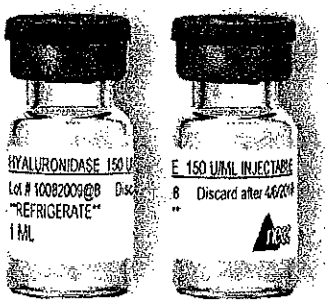
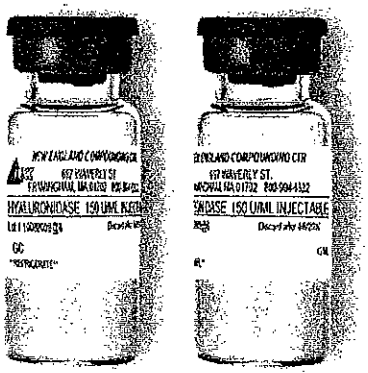
Hyaluronidase

- 150u/mL
- Provided in a 1mL or 10mL Sterile Vial
- Beyond Use Date: 180 Days
- Storage: Refrigerated





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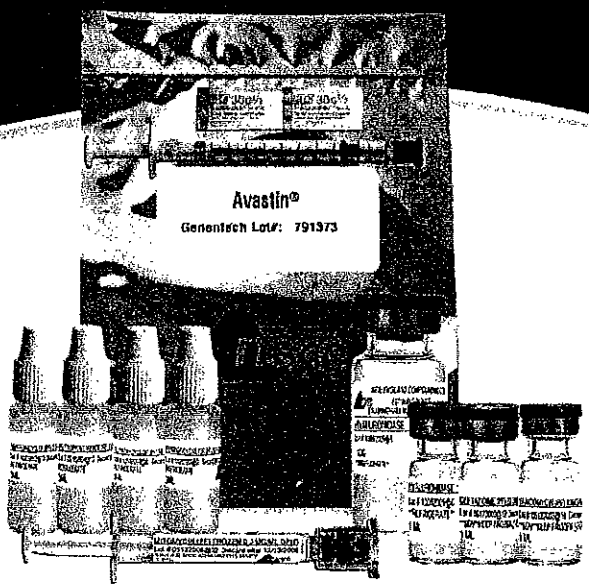

OPHTHALMOLOGY
CUSTOM MEDICATIONS

"Pre-Cataract" Dilation Drops (Preservative-Free)	(PE) Phenylephrine (T) Tropicamide (C) Cyclopentolate (K) Ketorolac #1) PE-T-C 2.5%-1%-1% #2) PE-T-C 10%-1%-1% #3) PE-T-C-K 2.5%-1%-1%-0.5% #4) PE-T-C-K 10%-1%-1%-0.5%
Avastin™ - "Unit-Dose Syringe"	1.25mg/0.05mL Syringe/ Needle/ Tamper-Evident, Light-Resistant Mylar Bag
Triamcinolone Acetonide	40mg/mL (PF), 1mL Vial
Frozen/Unit-Dose Antibiotics	Vancomycin 10mg/mL, 1mL Vial Ceftazidime 22.5mg/mL, 1mL Vial
Hyaluronidase	150u/mL, 1mL or 10mL Vial
Mitomycin	0.2-0.5mg/mL, 1mL Volume in a 3mL Syringe, "Frozen" Unit of Use

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UNIT-DOSE REPACKAGED RADIOPAQUE DYES

Aseptic Repackaging Service Provided by NECC

Repackaged Isovue™ or Omnipaque™ in a 5ml Sterile Vial

- USP 797 Compliant
- All sterile products are compounded for your patients by pharmacists extensively trained in aseptic compounding

NECC has earned a national reputation as a provider of high quality compounded medications and excellent service to patients and prescribers

Call us at 800.994.6322

www.neccrx.com

Belladonna Alkaloid/ Morphine* Suppositories

*Substitute for Opium

Available in Two Strengths:

(1) 16.2mg / 3.75mg (2) 16.2mg / 7.5mg

- *Beyond Use Date*: 180 Days
- *Storage*: Refrigerated (Cold-shipped)
- Minimum of #10 per Order
- CII - Original Prescription Required

All Formulations Are:

USP 797 / 795 Compliant

All formulations are compounded for your patients by pharmacists & technicians extensively trained in aseptic compounding

Medications are comprised of USP quality ingredients

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www.neccrx.com

Dilation Drops

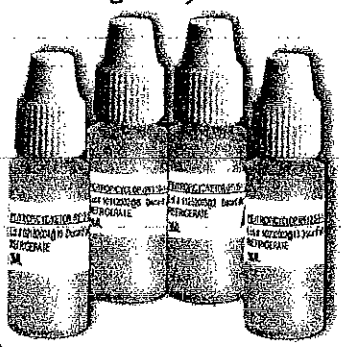
(Concentrated & Preservative-Free)

Is Dilating Your Patient's Eyes Driving Your Staff to Tears?

Four Popular Examples:

Combination 1	Combination 2	Combination 3	Combination 4
Tropicamide 1%	Tropicamide 1%	Tropicamide 1%	Tropicamide 1%
Cyclopentolate 1%	Cyclopentolate 1%	Cyclopentolate 1%	Cyclopentolate 1%
Phenylephrine 2.5%	Phenylephrine 10%	Phenylephrine 2.5%	Phenylephrine 10%
		Ketorolac 0.5%	Ketorolac 0.5%

Many regimens used to prepare a patient for cataract surgery require nurses to administer as many as 6 individual ophthalmic medications! NECC can help by compounding these agents into concentrated combinations that will greatly reduce the number of doses required to prepare the patient.



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Mitomycin

(For Ophthalmic Use)

- Sterile Solution Available in 0.2 - 0.5mg/mL or Customized Concentrations
- 1mL Volume Dispensed in a 3mL Syringe
- Beyond Use Date: 3 Months
- Storage: Frozen

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COMMITMENT TO QUALITY

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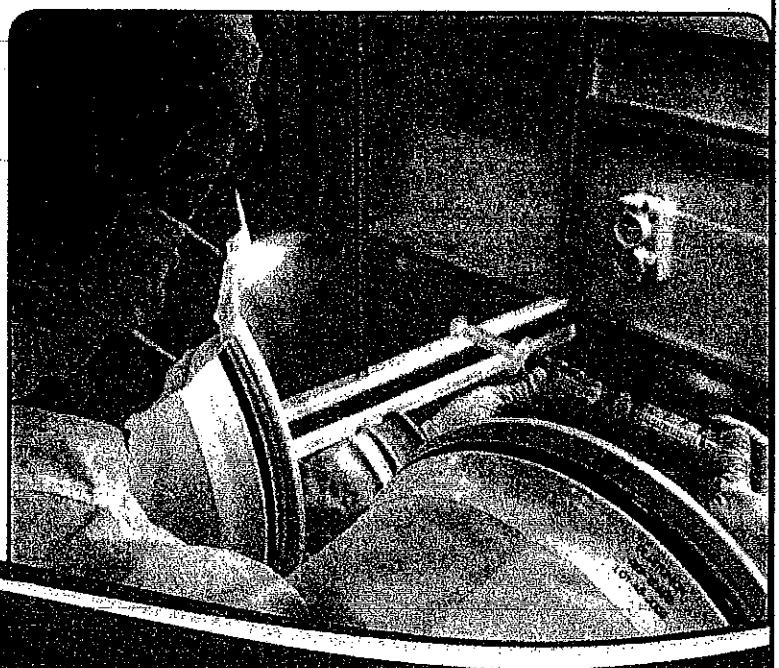
- Strictly Enforced Environmental Monitoring Program
- Comprehensive End-Product Testing Program

  (Independent Analytical Laboratory Used for ALL End-Product Testing)

  - Sterility Testing
  - Endotoxin Testing
  - Quantitative Testing
  - Extended Stability Testing



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Company Overview

NECC is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and service from our state-of-the-art facility

Compounding allows a practioner to prescribe and a pharmacist to prepare, medications that are:

- No longer manufactured
- Persistently backordered due to production shortages
- Not commercially available in the combination or dosage form the patient needs, i.e. preservative free

Why NECC?

- Complies with USP Chapter 797 Guidelines for Aseptic Compounding
- Our facility was designed and built as a compounding-only pharmacy with a strong focus on sterile products
- Sterile formulations are prepared in a Class 10 Microenvironment (barrier isolator)
- Chemicals are weighed on electronic analytical balances ensuring accuracy
- Our pharmacists:
  - Are licensed and registered by the Massachusetts Board of Registration in Pharmacy
  - Have completed American Council on Pharmaceutical Education (ACPE) accredited aseptic training courses
  - Follow national standards of practice for sterile product preparation as set forth by professional associations such as the American Society of Health-System Pharmacists (ASHP) and the United States Pharmacopeia (USP)
  - Are members of the International Academy of Compounding Pharmacists (IACP)
  - Use only the highest quality chemicals
  - Maintain extensive Environmental Testing and Quality Assurance Programs
  - Use an independent lab to test medications for sterility, potency and pyrogenicity

NECC has earned a national reputation as a provider of high quality compounded medications and excellent service to patients and prescribers

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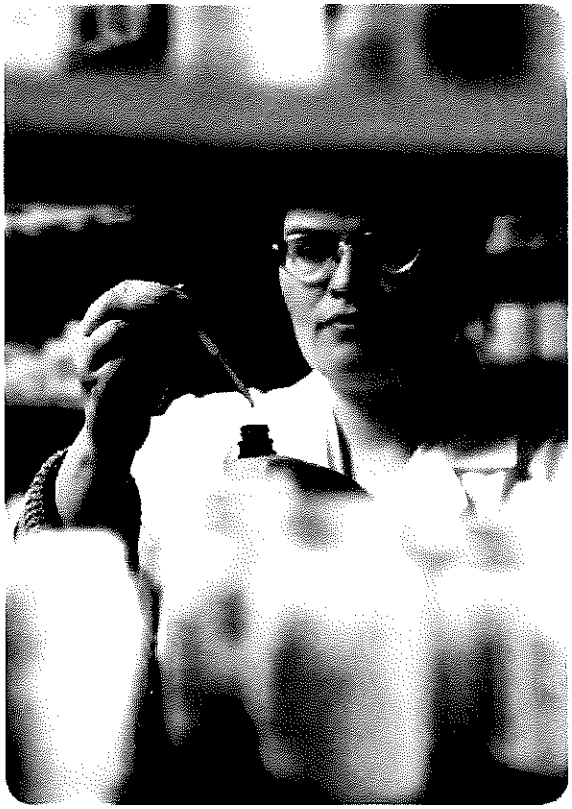
FDA Consumer Health Information
www.fda.gov/consumer/updates/compounding053107.html



Photodisc

The Special Risks of Pharmacy Compounding

Pharmacy compounding is an age-old practice in which pharmacists combine, mix, or alter ingredients to create unique medications that meet specific needs of individual patients.

It's also a practice that is under FDA scrutiny—mainly because of instances where compounded drugs have endangered public health.

"In its traditional form, pharmacy compounding is a vital service that helps many people, including those who are allergic to inactive ingredients in FDA-approved medicines, and others who need medications that are not available commercially," says Kathleen Anderson, Pharm.D, Deputy Director of the Division of New Drugs and Labeling Compliance in FDA's Center for Drug Evaluation and Research (CDER).

Compounded medications are also prescribed for children who may be unable to swallow pills, need diluted dosages of a drug made for adults, or are simply unwilling to take bad-tasting medicine.

"But consumers need to be aware that compounded drugs are not FDA-approved," Anderson says. "This means that FDA has not verified their safety and effectiveness."

Steve Silverman, Assistant Director of CDER's Office of Compliance, says that poor practices on the part of drug compounders can result in contamination or in products that don't possess the strength, quality, and purity required. "And because patients who use these drugs may have serious underlying health conditions," he says, "these flawed methods pose special risks."

Unlike commercial drug manufacturers, pharmacies aren't required to report adverse events associated with compounded drugs. "FDA learns of these through voluntary reporting, the media, and other sources," says Silverman.

The Agency knows of more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions.

- Three patients died of infections stemming from contaminated compounded solutions that are used to paralyze the heart during open-heart surgery. FDA issued a warning letter in March 2006 to the firm that compounded the solutions.
- Two patients at a Washington, D.C., Veterans Affairs hospital were blinded, and several others had their eyesight damaged, by a compounded product used in cataract surgery. The product was contaminated with bacteria. In August 2005, FDA announced a nationwide recall of this Trypan Blue Ophthalmic Solution. Contaminated solution had been

distributed to hospitals and clinics in eight states.
- In March 2005, FDA issued a nationwide alert concerning a contaminated, compounded magnesium sulfate solution that caused five cases of bacterial infections in a New Jersey hospital. A South Dakota patient treated with the product developed sepsis and died.

A Troubling Trend

The emergence over the past decade of firms with pharmacy licenses making and distributing unapproved new drugs in a way that's clearly outside the bounds of traditional pharmacy is of great concern to FDA.

"The methods of these companies seem far more consistent with those of drug manufacturers than with those of retail pharmacies," says Silverman. "Some firms make large amounts of compounded drugs that are copies or near copies of FDA-approved, commercially available drugs. Other firms sell to physicians and patients with whom they have only a remote professional relationship."

FDA highlighted these concerns in August 2006, when it warned three firms to stop manufacturing and distributing thousands of doses of compounded, unapproved inhalation drugs nationwide.

Inhalation drugs are used to treat diseases including asthma, emphysema, bronchitis, and cystic fibrosis. "These are potentially life-threatening conditions for which numerous FDA-approved drugs are available," says Silverman. "Compounded inhalation drugs may be distributed to patients in multiple states, and patients and their doctors may not understand that they are receiving compounded products."

Enforcement

"FDA historically hasn't directed enforcement against pharmacies engaged in traditional compounding," says Anderson. "Rather, we've focused on establishments whose activities raise the kinds of concerns normally associated with a drug manufacturer and whose compounding practices result in significant violations of the new-drug, adulteration, or misbranding provisions of the Federal Food, Drug, and Cosmetic Act."

FDA counts compounded drugs among the new drugs that are covered under the Act. "We consider them new because they're not generally recognized among experts as safe and effective," says Anderson.

She adds that FDA recognizes that states have a central role in regulating pharmacy compounding. "We refer complaints to the states, support them when they request it, and cooperate in investigations and follow-up actions. But there are cases when states are unable to act, and we proceed without them," Anderson says.

Red Flags

In a May 29, 2002, Compliance Policy Guide devoted to human pharmacy compounding, FDA identifies factors that it considers in deciding upon enforcement action. These factors include instances where pharmacists are:
- compounding drug products that have been pulled from the market because they were found to be unsafe or ineffective.
- compounding drugs that are essentially copies of a commercially available drug product.
- compounding drugs in advance of receiving prescriptions, except in very limited quantities relating to the amounts of drugs previously compounded based on valid prescriptions.
- compounding finished drugs from bulk active ingredients that aren't components of FDA-approved drugs, without an FDA-sanctioned, investigational new-drug application.
- receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
- failing to conform to applicable state law regulating the practice of pharmacy.

What You Can Do

What can consumers do to protect themselves against inappropriate drug-compounding practices? Ilisa Bernstein, Pharm.D, J.D., Director of Pharmacy Affairs in FDA's Office of the Commissioner, offers these tips:
- Ask your doctor if an FDA-approved drug is available and appropriate for your treatment.
- Check with the pharmacist to see if he or she is familiar with compounding the product in your prescription.
- Get information from your doctor or pharmacist about proper use and storage of the compounded product.
- If you receive a compounded product, ask the pharmacist if the doctor asked for it to be compounded.
- If you experience any problems or adverse events, contact your doctor or pharmacist immediately and stop using the product.
- Report any adverse events experienced while using the product to FDA's MedWatch program at *http://www.fda.gov/medwatch/* FDA

MMWR™
Morbidity and Mortality Weekly Report

Weekly December 13, 2002 / Vol. 51 / No. 49

Exophiala Infection from Contaminated Injectable Steroids Prepared by a Compounding Pharmacy — United States, July–November 2002

In the United States, pharmacists compound medications to meet unique patient drug requirements or to prepare drug products that are not available commercially (*1*). In September 2002, the North Carolina Division of Public Health (NCDPH) was notified of two cases of meningitis caused by a rare fungus in patients who had received epidural injections at outpatient pain management clinics. This report describes five cases of fungal infection associated with contaminated drugs prepared at a compounding pharmacy. Clinicians should consider the possibility of improperly compounded medications as a source of infection in patients after epidural or intra-articular injections.

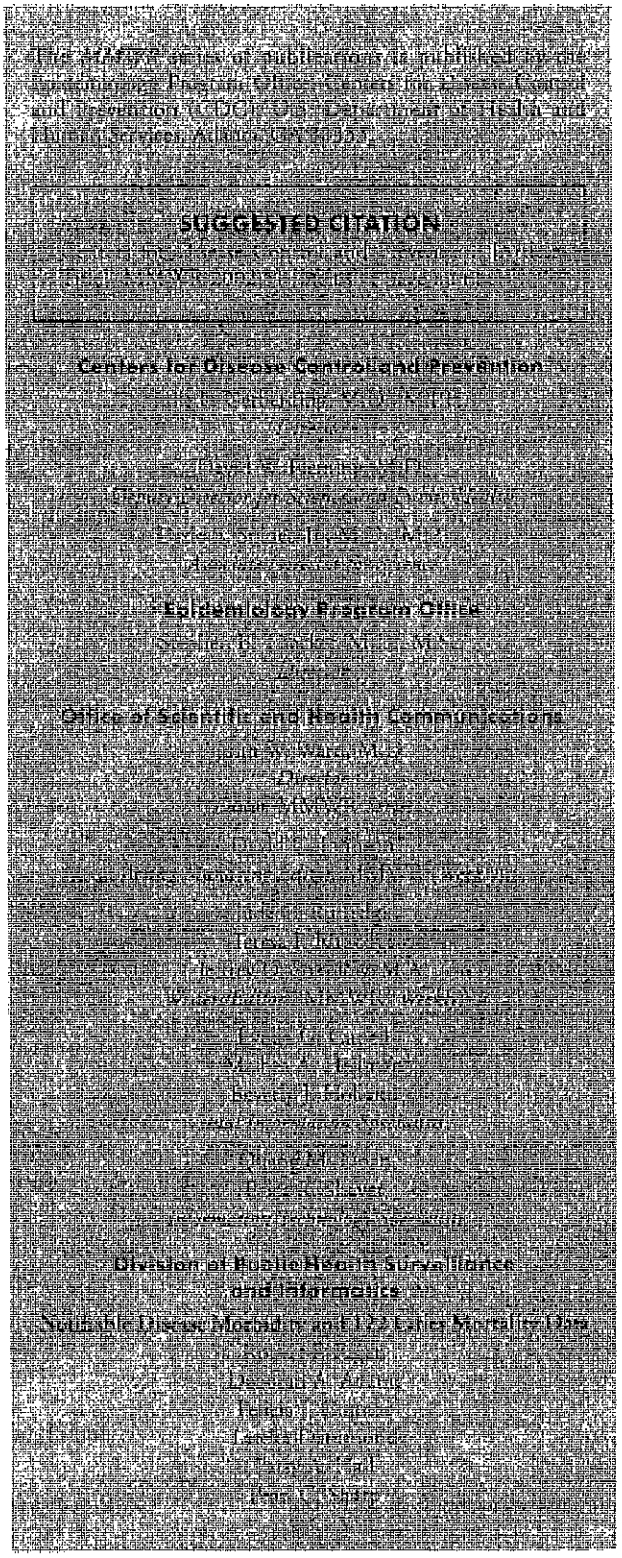
Case Reports

Case 1. On July 5, 2002, a woman aged 77 years with chronic low back pain was admitted to hospital A in North Carolina with a 4-day history of progressive diffuse headache, fever, chills, and malaise with subsequent development of vertigo, nausea, and vomiting. She was febrile (100.4° F [38.0°C]) and had slight nuchal rigidity. Analysis of cerebrospinal fluid (CSF) was consistent with meningitis: 979 white blood cells (WBC)/mm^3 (normal: <10 WBC/mm^3) with 63% neutrophils, protein of 134 mg/dL (normal: 15–45 mg/dL), and glucose of 38 mg/dL (normal: 40–80 mg/dL). The patient showed no improvement on antibacterial drugs, and a follow-up CSF analysis on July 18 revealed yeast-like elements on microscopic examination. The patient was treated with amphotericin B and transferred to hospital B in North Carolina. On July 24, a fungus cultured from CSF was identified as *Exophiala* (*Wangiella*) *dermatitidis*. Amphotericin B was discontinued, and voriconazole and flucytosine were started. The patient's condition continued to deteriorate, and she died 51 days after hospitalization. The patient had been treated at pain management clinic A in North Carolina and had received lumbar epidural injections with methylprednisolone acetate 100 and 35 days before hospital admission. The injectable methylprednisolone had been prepared by compounding pharmacy A in South Carolina.

Case 2. On August 14, 2002, a woman aged 61 years who was being treated for chronic low back pain at pain management clinic A was admitted to hospital A after CSF obtained during a myelogram was consistent with meningitis (820 WBC/mm^3 with 52% neutrophils, protein of 108 mg/dL, and glucose of 57 mg/dL). The patient had a 3–5 day history of mild headache, subjective fever, chills, sweats, and mild neck stiffness. The patient had received lumbar epidural injections at pain management clinic A 84 and 34 days before hospital admission. The injections contained methylprednisolone acetate prepared by compounding pharmacy A. CSF grew yeast, later identified as *E. dermatitidis*, 27 days after collection. The patient was begun on intravenous voriconazole and later switched to oral voriconazole; as of December 5 (70 days into therapy), she has improved.

Additional cases. Clinicians from hospital A notified NCDPH of the two cases of *E. dermatitidis* meningitis; three additional cases have been identified. Case 3 occurred in a woman aged 71 years who had *E. dermatitidis* meningitis. She was admitted to hospital B in North Carolina on July 8 and had received epidural methylprednisolone acetate injections at pain management clinic B 82, 55, and 35 days before

INSIDE



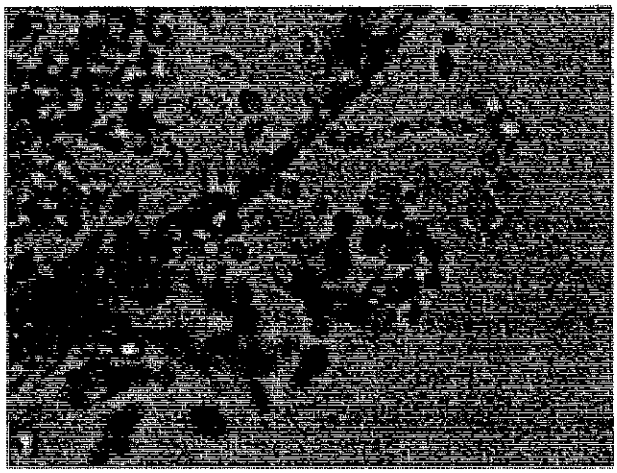
hospitalization. Case 4 occurred in a woman aged 65 years who had *E. dermatitidis* meningitis. She was admitted to hospital C in North Carolina on October 8 and had received epidural methylprednisolone acetate injections at pain management clinic A 116 days before hospitalization. Case 5 occurred in a woman aged 52 years who had *E. dermatitidis* sacroiliitis. She was admitted to hospital D in North Carolina on November 4 and had received intra-articular methylprednisolone acetate injections at pain management clinic B 103 and 152 days before hospitalization.

Investigation of Compounding Pharmacy A

Compounding pharmacy A was the source of the methylprednisolone acetate administered to all five patients with *Exophiala* infections. The pharmacy had been supplying the compounded product to hospitals and pain management clinics in five states after a proprietary form of methylprednisolone acetate injectable suspension (Depo Medrol®, Pharmacia Corp., Peapack, New Jersey) became difficult to obtain from the manufacturer. An investigation of compounding pharmacy A by the South Carolina Board of Pharmacy (SCBP) found improper performance of an autoclave with no written procedures for autoclave operation, no testing for sterility or appropriate checking of quality indicators, and inadequate clean-room practices as outlined in the American Society of Health-System Pharmacists (ASHP) guidance for pharmacy-prepared sterile products (*2*). Microbiologic culture at CDC and the Food and Drug Administration (FDA) of unopened vials from three separate lots of injectable methylprednisolone obtained from compounding pharmacy A yielded *E. dermatitidis* (Figure). On September 27, SCBP ordered the pharmacy to halt further sale of compounded drug products. Injectable drugs had been distributed to physicians, hospitals, clinics, and consumers in 11 states (Connecticut, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Mississippi, New Hampshire, North Carolina, South Carolina, and Virginia). FDA inspection of the compounding facility revealed that the firm failed to have adequate controls to ensure necessary sterility, including the absence of appropriate testing for potency and sterility before distribution. On November 15, based on the lack of assurance that the pharmacy's products were sterile, FDA announced a nationwide alert about all injectable drug products prepared by the pharmacy.

All sites that received injectable methylprednisolone prepared by compounding pharmacy A have been contacted and have returned all unused products for testing. Treating clinicians were informed of the investigation of the adulterated product. In two states, patients who might have received the product were sent letters directing them to seek medical

FIGURE. Slide culture of *Exophiala (Wangiella) dermatitidis* stained with lactophenol blue demonstrating conidial structure and numerous budding cells, magnified by 1,000



attention if they developed symptoms, and laboratories were instructed to notify state officials if they isolated *E. dermatitidis* from clinical specimens.

Reported by: *J Engemann, MD, K Kaye, MD, G Cox, MD, J Perfect, MD, W Schell, MS, SA McGarry, MD, Duke Univ, Durham; K Patterson, MD, S Edupuganti, MD, Univ of North Carolina, Chapel Hill; P Cook, MD, East Carolina Univ, Greenville; WA Rutala, PhD, DJ Weber, MD, KK Hoffmann, MS, Statewide Program in Infection Control and Epidemiology and Univ of North Carolina, Chapel Hill; J Engel, MD, North Carolina State Dept of Health and Human Svcs, Raleigh, North Carolina. S Young, E Durant, K McKinnon, N Cobb, South Carolina Board of Pharmacy, Columbia; L Bell, MD, J Gibson, MD, South Carolina Dept of Health and Environmental Control. D Jernigan, MD, M Arduino, PhD, S Fridkin, MD, L Archibald, MD, L Schulster, PhD, Div of Healthcare Quality Promotion; J Morgan, MD, R Hajjeh, MD, M Brandt, PhD, D Warnock, PhD, Div of Bacterial and Mycotic Diseases, National Center for Infectious Diseases; WA Duffus, MD, EIS Officer, CDC.*

Editorial Note: As of December 5, five cases of *Exophiala* infection associated with injectable medication from compounding pharmacy A had occurred. Cases occurred up to 152 days following an injection.

Pharmacy compounding is the process of combining drug ingredients to prepare medications that are not commercially available or to alter commercially available medications to meet specific patient needs such as dye-free or liquid formulations (*3*). The practice of compounding has been reported to be increasing with an estimated 43,000 compounded medications prepared daily in the United States (*4,5*). Pharmacists traditionally have prepared medications to fulfill individual prescription requests or manipulated reasonable quantities of human drugs on receipt of a valid prescription for an individually identified patient from a licensed practitioner. Some compounding is legal under state laws, and, when appropriate, FDA can exercise its enforcement discretion regarding new drugs and certain other requirements of the federal Food, Drug, and Cosmetic Act (*6*).

On-site investigation of compounding pharmacy A by state and federal regulators identified several instances of nonadherence to sterile technique. Microbiologic cultures at CDC and FDA of methylprednisolone from unopened vials prepared by compounding pharmacy A yielded isolates of *E. dermatitidis*. This fungus caused the death from meningitis in one patient, sacroiliitis in another, and meningitis in three other patients who had received either epidural or intra-articular injections of methylprednisolone compounded at pharmacy A. Other recent clusters of infections associated with products prepared by compounding pharmacies include *Serratia* meningitis from epidural injections of betamethasone in California (Contra Costa Health Services, unpublished data, 2002) and *Chryseomonas* meningitis from epidural injections of methylprednisolone in Michigan (CDC, unpublished data, 2002). These meningitis clusters all occurred among patients who received epidural injections for chronic pain management.

E. dermatitidis is a neurotropic, dark pigment-forming fungus found in soil and is an uncommon cause of human illness (*7*). Limited data are available on treatment; however, in vitro data suggest that amphotericin B, itraconazole, terbinafine, and voriconazole might be effective (*8*). Isolates from four of the five infected persons reported were tested in vitro and were susceptible to voriconazole, itraconazole, and amphotericin B. Voriconazole was chosen for treating the five persons reported because of in vitro susceptibility results and availability of an oral form of the drug.

Clinicians or laboratorians diagnosing any cases of *Exophiala* should determine if the patient had received injections of methylprednisolone in the last year. Although the implicated product has been recalled, clinicians should be aware that cases might still occur because of the possible long incubation period of the fungal infection. Patients with possible injection-associated *Exophiala* infections should be reported to their state health department and to CDC, telephone 800-893-0485; such information should be exchanged rapidly with other state and local health departments. Clinicians should consider the possibility of contaminated medication as a source of infection in patients after epidural or intra-articular injections. Compounding pharmacies should ensure that pharmacy staff are trained appropriately and that proper sterile technique is followed in accordance with existing standards from ASHP (*2*) and the United States Pharmacopeia (http://www.usp.org). FDA has outlined specific activities that

help distinguish the role of compounding pharmacies from pharmaceutical manufacturing (*4*).

Some health-system pharmacists might not realize that they are purchasing injectables prepared through compounding (*1*). Purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that is licensed in their state and that follows appropriate measures to ensure that injectable products are free of contamination. In most states, compounding pharmacies are not required to report adverse events associated with their products to state or federal agencies. Such reporting to FDA is required for pharmaceutical manufacturing companies. Health-care professionals and compounding pharmacies are urged to report contaminated compounded drug products or adverse events associated with compounded drug products to their state boards of pharmacy and health departments. To help prevent further cases, practitioners also are encouraged to submit such reports to FDA's MedWatch program by telephone at 1-800-332-1088 or at http://www.fda.gov/medwatch/report.htm.

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Outbreaks of Gastroenteritis Associated with Noroviruses on Cruise Ships — United States, 2002

During January 1–December 2, 2002, CDC's Vessel Sanitation Program (VSP), which conducts surveillance for acute gastroenteritis (AGE) on cruise ships with foreign itineraries sailing into U.S. ports (*1*), received reports of 21 outbreaks of AGE* on 17 cruise ships. Of the 21 outbreaks, nine were confirmed by laboratory analysis of stool specimens from affected persons to be associated with noroviruses, three were attributable to bacterial agents, and nine were of unknown etiology. Seven outbreaks were reported in 2001, and of these, four were confirmed to be associated with norovirus (CDC, unpublished data, 2002). This report describes five of the norovirus outbreaks that occurred during July 1–December 2, 2002, on cruise ships.

Outbreaks

Cruise Ship A. On July 18, cruise ship A, owned by cruise line A, embarked 1,318 passengers and 564 crew members for a 7-day cruise from Vancouver to Alaska. On July 19, five passengers reported to the ship's infirmary with symptoms of AGE (Figure 1). By July 25, a total of 167 (13%) passengers and nine (2%) crew members had reported illness. Among the 176 patients, the predominant symptoms were vomiting (76%) and diarrhea (73%). Five of 10 stool specimens from ill passengers were positive for norovirus by reverse transcriptase polymerase chain reaction (RT-PCR). On July 25, when passengers disembarked, the ship was disinfected in accordance with CDC recommendations, and the same day, a new group of passengers embarked for another 7-day cruise. During the cruise, 189 (14%) of 1,336 passengers and 30 (5.3%) of 571 crew members had AGE with diarrhea (91%) and vomiting (85%) (Figure 1). An environmental health inspection conducted by CDC revealed no sanitary deficiencies. Cruise line A cancelled a subsequent cruise and voluntarily took the ship out of service for 1 week for aggressive cleaning and sanitizing. No outbreaks were reported on subsequent cruises.

Cruise Ship B. On October 1, cruise ship B, also owned by cruise line A, embarked 1,281 passengers and 598 crew members for a 21-day cruise from Washington to Florida. By October 16, a total of 101 (8%) passengers and 14 (2%) crew members reported to the infirmary with AGE symptoms. On October 18, CDC investigators boarded the ship to conduct an epidemiologic and environmental investigation. Of 972 surveyed passengers, 399 (41%) met the case definition for AGE. Investigators found no association between illness and water, specific meals served on the ship, or with offshore excursions. Stool specimens from 12 of 13 patients tested posi-

*An outbreak of AGE was defined as one in which ≥3% of passengers or crew members report illness (defined as three or more episodes of loose stools in a 24-hour period or as vomiting with one additional symptom such as abdominal cramps, headache, myalgia, or fever). The evaluation of an outbreak might consist of environmental, epidemiologic, and laboratory investigative components, including an epidemic survey distributed to passengers and crew members, environmental sampling, and collection of stool specimens from patients.